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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/493,891	01/28/00	LONGTON W	LEH-35B-98

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HM12/1024

EXAMINER	
MAIER, L	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/493,891	Longton
Examiner	**Art Unit**
Leigh Maier	1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 6, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-14* is/are pending in the applica

4a) Of the above, claim(s) *1, 2, and 10-14* is/are withdrawn from considera

5) ☒ Claim(s) *3-9* is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

Applicant's election with traverse of group II, claims 3-9 in Paper No. 5 is acknowledged. The traversal is on the ground that inventions II and III are classified in the same class and subclass, and a search for both sets of claims would not be burdensome. This is not found persuasive because although they are classified together in the U.S. Classification system, a search of issued U.S. patents is comprises only part of a thorough search of the art in the examination of claims. Also included is a search of foreign patents and non-patent literature. Furthermore, these inventions are drawn to two separate reaction processes. Although they are nominally linked by the fact that the product of invention II can be used for, among other things, the starting material for invention III, the starting material for group III can be made by other methods. The search for the two inventions would therefore not be co-extensive.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites a Markush group of polysaccharide carboxylic acids. However, the group includes chitosan, a non-carboxylic acid. The inclusion of this species renders the claim vague and indefinite, as it is not clear exactly what polysaccharides are being contemplated in the invention.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by HEINDEL et al (Bioconjugate Chem., 1994).

HEINDEL discloses the preparation of carboxymethyl dextran lactone by thermal dehydration of carboxymethyl dextran in an anhydrous, non-nucleophilic solvent (toluene, xylenes, diglyme, or acetonitrile). See paragraph bridging pages 98 and 99.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by AKANUMA et al (J. Biochem., 1978).

AKANUMA discloses the preparation of carboxymethyl dextran lactone by thermal dehydration of CM-dextran and CM-cellulose in non-nucleophilic solvent. See page 1358, right hand column, and paragraph bridging pp 1360-1. AKANUMA is silent on whether or not the solvent used in the process is anhydrous, but the product appears to be otherwise identical to that claimed. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product-by-process and the product of the prior art. See In re Best, 562 F.d. 1252, 195 USPO 430 (CCA 1977) and In re Fitzgerald, 619 F.d. 67, 205 USPO 594 (CCA 1980).

Claim 9 is rejected under 35 U.S.C. 102(a) as being anticipated by MARTEY et al (CAPLUS abstract 1998:529836, 1998).

MARTEY discloses the dehydration of carboxymethylated dextran and cellulose to prepare a lactone product. MARTEY is silent on the identity of the solvent used in the process, but the product appears to be otherwise identical to that claimed. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed

product-by-process and the product of the prior art. See In re Best, 562 F.d. 1252, 195 USPO 430 (CCA 1977) and In re Fitzgerald, 619 F.d. 67, 205 USPO 594 (CCA 1980).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 4, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over AKANUMA et al (J. Biochem., 1978).

The claims are drawn to a method of lactonizing a finely ground polysaccharide carboxylic acid by thermal dehydration of the precursor polysaccharide in the presence of an anhydrous non-nucleophilic solvent.

AKANUMA teaches as set forth above.

As noted above, the reference is silent about the water content, or lack thereof, of the solvent. It would have been obvious to one having ordinary skill in the art to have used an anhydrous solvent. The lactonization process produces, so the artisan would be motivated to minimize water in the starting material to move the equilibrium in favor of the products. It would be further obvious to use finely ground precursor polysaccharide to facilitate suspension of the material in the solvent.

Claims 3-6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over HEINDEL et al (Bioconjugate Chem., 1994) and AKANUMA et al (J. Biochem., 1978).

The invention is as set forth above. Dependent claims recite the use of the species CM-cellulose.

HEINDEL teaches as set forth above. Although HEINDEL does not describe the CM-dextran starting material as "finely ground," it is believed that the CMD used would meet this limitation. However, even if it did not, it would have been obvious to use finely ground CMD to facilitate suspension in the solvent.

AKUNUMA teaches as set forth above. The reference further teaches the lactonization of CM-cellulose to prepare hydrazide derivatives.

It would have been obvious to one having ordinary skill in the art to use the HEINDEL process to lactonize CM-cellulose for its art disclosed utility.

Claims 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over HEINDEL et al (Bioconjugate Chem., 1994) and AKANUMA et al (J. Biochem., 1978) in further view of MILL et al (US 4,003,792).

The invention is as set forth above. Dependent claims recite the use of other polysaccharide species.

HEINDEL and AKANUMA teach as set forth above. Both references teach the preparation of lactones as intermediates preparation of polysaccharide bioconjugates. Together, the references do not teach the full range of polysaccharides recited.

MILL teaches that a wide variety of carboxylic acid polysaccharides, such as pectin, have utility in preparing polysaccharide bioconjugates.

It would have been obvious to one having ordinary skill in the art to lactonize any biocompatible carboxylic acid polysaccharide using the HEINDEL process for their art-disclosed utility in the preparation of bioconjugates.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Monday-Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist (703) 308-1701, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
October 17, 2001

KATHLEEN K. FONDA
PRIMARY EXAMINER